

Appl. No. 09/986,775  
Amdt. dated October 3, 2003  
Reply to Office Action of June 17, 2003

### **REMARKS**

Reconsideration and allowance of the above-identified application are respectfully requested. Upon entry of this Amendment, claims 28, 36-38, 42 and 43 will be amended and claim 32 will be canceled, leaving claims 1-31 and 33-44 pending, with claims 1, 15, 28 and 37 being independent. Claims 1-27 have been withdrawn from consideration by the Examiner.

### **Election/Restriction**

Applicant reaffirms the belief that the restriction/election is improper and requests that it be withdrawn for the reasons and arguments set forth in the March 17, 2003 response.

### **Rejections Under 35 U.S.C. §112, second paragraph**

Claims 36-44 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Examiner contends that the recitation of the phrases “a mark on the center on the inlay” and “axes extending from the center of the inlay in a direction toward the periphery of the inlay” in claim 36 lack antecedent basis. As noted above, claim 36 has been amended to overcome this rejection.

Additionally, the Examiner contends that the limitation "said markings" in line 3 of claim 37 lacks antecedent basis. As noted above, claim 37 has been amended to overcome this rejection.

Furthermore, the Examiner contends that the limitation "said corresponding marking on the surface of the cornea" in dependent claim 42 lacks antecedent basis. Applicant respectfully disagrees and notes that base claim 37 recites "a corresponding marking on the surface of the cornea". The Examiner also contends that claiming markings on the cornea is improper, since this would be positively claiming a portion of the body, which is non-statutory subject matter.

Applicant respectfully notes that the cornea is not being positively claimed, but merely the markings on the surface of the cornea that can be aligned with corresponding markings on the inlay.

**Rejections Under 35 U.S.C. §102(e)**

Claims 28, 30-33, 37, 38 and 41-43 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Pub. No. US 2002/0029981 to Nigam. The Examiner contends that the Nigam Application discloses all of the elements of these claims.

Clearly, the Nigam Application does not disclose, teach or suggest all of the elements of amended independent claim 28. Specifically, the Nigam Application does not disclose, teach or

suggest a removable, pliable sheet of material directly adjacent and conforming to the second surface of the inlay, as recited in independent claim 28.

The Nigam Application discloses an applicator 45 that has an arcuate surface 42, which matches that of the cornea, thus enabling the implant to be more evenly deposited on the corneal surface. (page 4, paragraphs 0049 and 0055). There is no disclosure that the surface 42 is pliable and can conform to the shape of the surface of the implant. In fact, the opposite appears to be the case. As shown in Figs. 14a-e, it appears that the surface 42 of the applicator 45 is rigid and the surface of the implant conforms to the surface of the applicator. This teaches away from the claimed embodiment of the present invention and demonstrates that the Nigam applicator differs structurally from the claimed embodiment.

Therefore, Applicant submits that amended independent claim 28 and its dependent claims 29-31 and 33-36 are allowable. Moreover, certain dependent claims recite additional features that further distinguish them from the cited reference. For example, claim 29 recites that the markings on the removable sheet are at least ten radial axes extending from about the center of the inlay in a direction of the periphery of the inlay. Claim 36 recites that the inlay has markings thereon, which include a mark on the center of the inlay and at least two radial axes extending from the center of the inlay in a direction toward the periphery of the inlay, and the markings are adapted to align with respective markings on the surface of the cornea.

Amended independent claim 37 recites, among other things, an inlay having removable markings thereon that extend along at least one radial axis thereof, with the inlay markings aligning with a corresponding marking on the surface of the cornea.

As noted in the Office Action, the Nigam Application does not disclose this feature. Additionally, contrary to the contentions of the Examiner, Applicant submits that it would not have been obvious to modify the Nigam invention with the markings of the present invention.

Specifically, although the alleged “marks” taught by the Nigam application, openings 23 and 22, for example, are used for assisting in alignment, they are clearly not aligned with corresponding markings on the cornea. As noted on page 4, para. 0049 of the Nigam Application, the central opening 23 uses the pupil diameter to assist in alignment. There is no teaching or suggestion that any portion of the eye could be marked with a mark that corresponds to a removable marking on a surface of an inlay that extends along at least one radial axis of the inlay surface. Any motivation to mark the cornea in this manner would be ascertained via improper hindsight.

Claims 37 and 41-44 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,102,946 to Nigam. The Examiner believes that the Nigam patent discloses all of the elements of these claims.

Clearly, the Nigam patent does not disclose, teach or suggest all of the elements of amended independent claim 37. Specifically, the Nigam patent does not disclose, teach or

suggest an inlay having removable markings thereon that extend along at least one radial axis thereof, with the inlay markings being adapted to align with a corresponding marking on the surface of the cornea, as recited in independent claim 37.

The Nigam patent discloses tabs 76a and 76b and indentations 78a and 78b only at the periphery that are used to identify an axis of the implant to maintain proper alignment. However, there is no disclosure, teaching or suggestion in the Nigam patent that there are markings on the cornea, with which the implant markings could or do align. Additionally, there is no disclosure that the markings extend along a radial axis (i.e., form a line along a radial axis of the inlay.). The Nigam patent merely shows axes X and Y as representations in the figures of the patent to indicate that there could be different dioptric powers on different areas of the lens. These X and Y axes are not markings on the actual lens. The only alignment assists on the lens are tabs 76a and 76b and indentations 78a and 78b.

By only having these tabs 76a and 76b, the Nigam patent can only be aligned about its own axis. In other words, the surgeon can identify the proper rotational orientation to implant the implant; however, the surgeon cannot identify the proper position relative to the cornea.

In the present invention, as recited in independent claim 37, the inlay can be properly oriented with respect to its own rotational alignment and can be properly positioned due to the markings aligning with a corresponding marking on the surface of the cornea. There is no

disclosure in the Nigam patent that tabs 76a and 76b could be aligned with corresponding markings on the surface of the cornea.

Therefore, Applicant submits that amended independent claim 37 and its dependent claims 38-44 are allowable over the cited prior art.

Claims 28, 32, 33, 37, 38 and 43 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,655,774 to Choyce. The Examiner believes that the Choyce patent discloses all of the elements of these claims.

Clearly, the Choyce patent does not disclose, teach or suggest all of the elements of amended independent claims 28 and 37. Specifically, the Choyce patent does not disclose, teach or suggest a removable, pliable sheet of material directly adjacent the second surface of an inlay, such that the sheet also overlies and conforms to the second surface of the inlay, as recited in independent claim 28. The Choyce patent also does not teach or suggest removable markings on a surface of an inlay that extend along at least one radial axis thereof, with the inlay markings aligning with a corresponding marking on the surface of the cornea.

The Choyce patent discloses a ring-shaped instrument that is laid over the eye and serves exclusively to assist in visual alignment. With regard to independent claim 28, there is no disclosure or suggestion that the Choyce instrument is pliable to conform to the surface of the inlay, and clearly the instrument is not directly adjacent the surface of the inlay. In fact, the

instrument is specifically placed on the exterior surface of the cornea, and not directly adjacent the surface of the inlay.

Additionally, it would not have been obvious to modify the Choyce instrument so that it could be positioned directly adjacent the surface of the inlay, since it would be necessary to increase the size of the opening formed in the cornea. This would cause a greater intrusion into the cornea of the eye, which the Choyce disclosure indicates is a problem with the prior art of kerato-prosthesis.

With regard to independent claim 37, there is no disclosure to suggestion in the Choyce patent of removable markings on a surface of an inlay that extend along at least one radial axis thereof, with the inlay markings aligning with a corresponding marking on the surface of the cornea.

As noted above, the Choyce patent discloses a ring shaped instrument that is positioned concentric with the ring of the sclera. There is clearly an opening in the center of the instrument, and therefore not only is there no disclosure of a marking extending along a radial axis, but such a marking would not be possible.

Furthermore, it would not have been obvious to put radial markings, as recited in claim 37, on the Choyce instrument, since it would be necessary to redesign the instrument into a disc shaped instrument. There is no suggestion or motivation to perform such a redesign and in fact, the Choyce patent teaches away from this type of redesign. As disclosed in col. 2, lines 63-68,

the Choyce instrument is to be positioned concentric with the ring in the sclera to assist in visual alignment. This visual alignment appears to occur by matching the inner radius of the ring shaped instrument with the outer diameter of the implant. Therefore, if one were to form a disc shaped instrument, this would render the Choyce instrument inoperative.

Additionally, the Choyce patent does not disclose, teach or suggest aligning the instrument with markings on the cornea. Any suggestion to mark the cornea and align the Choyce instrument in this manner would be improper hindsight.

Therefore, Applicant submits that amended independent claims 28 and 37, and their respective dependent claims 29-31 and 33-36 and 38-44, are allowable.

Claims 37 and 41-44 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,452,235 to Reynolds. The Examiner contends that the Reynolds patent discloses all of the elements of these claims.

Clearly, the Reynolds patent does not disclose, teach or suggest all of the elements of amended independent claim 37. Specifically, the Reynolds patent does not disclose, teach or suggest an inlay having removable markings thereon that extend along at least one radial axis thereof, with the inlay markings aligning with a corresponding marking on the surface of the cornea, as recited in independent claim 37.



The Reynolds patent discloses a method of implanting and adjusting ring 47. In the method, optical measurements are taken of the eye, and a target image comprised of indicia 81 is made by reflecting light from placido rings. Once the implant is inserted in the cornea, the diameter of the ring is adjusted to bring the ring into coincidence with the indicia 81.

The Reynolds patent does not disclose or suggest that the indicia are a removable marking on the surface of the inlay. At best, the indicia are reflected onto the external surface of the cornea, and not the surface of the inlay. Additionally, there is no disclosure or suggestion that these indicia align with corresponding markings either on the inlay or on another portion of the cornea.

Assuming, *arguendo*, that these are markings on the surface of the inlay, the indicia are not markings that extend along a radial axis of the inlay. Clearly the indicia are vertical lines or grids 81 that are tangential to radial lines or circumferential with respect to radial lines. These vertical lines or circumferential lines, although possibly allowing orientation with respect to a position on the cornea, do not allow rotational orientation of the implant.

Furthermore, assuming *arguendo*, that the indicia 81 or 93 are markings on the surface of the inlay, they would not move when the inlay moved. In other words, the markings do not and can not align with a corresponding marking on the surface of the cornea. To have removable inlay markings align with a corresponding marking on the surface of the cornea, there must be

two sets of markings that must be able to be moved independent from each other. The Choyce patent does not disclose, teach or suggest such markings.

It would not have been obvious to form markings as recited in claim 37 in the Reynolds invention, since the indicia 82 and 83 adequately allow the specific structure of the ring 47 to be properly implanted. There is no disclosure in the Choyce patent of a toric shaped inlay that would require proper rotational orientation.

#### **Rejections Under 35 U.S.C. §103(a)**

Claims 29, 34-36, 39, 40 and 44 stand rejected under 35 U.S.C. §103(a) as being obvious over the Nigam Application Publication.

As argued above, Applicant submits that the Nigam Application does not disclose, teach or suggest all of the elements of the independent claims from which each of these claims depend, i.e., independent claims 28 and 37. Specifically, the Nigam Application does not disclose, teach or suggest a removable, pliable sheet of material directly adjacent and conforming to the second surface of the inlay, as recited in independent claim 28, nor does the Nigam Application disclose, teach or suggest an inlay having removable markings thereon that extend along at least one radial axis thereof, the inlay markings aligning with a corresponding marking on the surface of the cornea, as recited in independent claim 37.

Appl. No. 09/986,775  
Amdt. dated October 3, 2003  
Reply to Office Action of June 17, 2003

Therefore, Applicant submits that independent claims 28 and 37, and their respective dependent claims are allowable for the reasons discussed above.

Prompt and favorable action is solicited. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the number listed below.

Respectfully submitted,

  
\_\_\_\_\_  
Jeffrey J. Howell  
Reg. No. 46,402  
Attorney for Applicant

Roylance, Abrams, Berdo & Goodman, L.L.P.  
1300 19th Street, N.W., Suite 600  
Washington, D.C. 20036-1649  
(202) 659-9076

Dated: October 3, 2003